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Phase II study of uPAR-PET in neuroendocrine tumor patients demonstrates strong prognostic value and supports potential future use of uPAR-targeted radionuclide therapy

Results from an investigator-initiated phase II study performed by researchers at Rigshospitalet using the uTRACE® technology have now been published online ahead of print in the prestigious Journal of Nuclear Medicine. The study demonstrates strong prognostic value and that uPAR is expressed in the majority of neuroendocrine tumor patients. The abstract of the article is freely available <u>here</u>.

The phase II study

The phase II trial (NCT03278275) aimed to evaluate the expression of uPAR in neuroendocrine tumor (NET) patients as well as the prognostic value of uPAR-PET with ⁶⁸Ga-NOTA-AE105 (uTRACE®). A total of 96 patients of all tumor grades were included and followed for a median of 28 months. The main findings were; 1) the majority, 68%, of all patients and 75% of patients with high grade (NEN G3) tumors had uPAR positive lesions indicating that uPAR as a target for targeted radionuclide therapy may be relevant for the majority of NET patients and notably also for high grade patients, and 2) that uPAR-PET could be used for prognostication both with regard to progression-free survival and overall survival. The authors suggested that "uPAR PET is relevant for risk stratification and uPAR may be a promising target for therapy in patients with NEN".

About neuroendocrine tumors

Each year approximately 35,000 new cases are diagnosed in the US and EU. Due to the long survival of these patients, more than 400,000 patients are living with the disease in the US and EU. Neuroendocrine tumors are a rare form of cancer that occurs in glandular cells most frequently in the lining of the gastrointestinal tract or in the lungs, but the disease can in principle occur in all organs of the body.

About Journal of Nuclear Medicine

The Journal of Nuclear Medicine is the official publication of the Society for Nuclear Medicine and Molecular Imaging and the highest-ranked journal within nuclear medicine based on the number of citations (impact factor).

"We are very excited about the positive data from the phase II study in neuroendocrine tumors patients using the uTRACE® technology that has been published by researcher from Rigshospitalet. Positive results from yet another type of cancer not only underscore that uPAR-PET is a platform technology that can be used across cancer types, but the data also supports the previous findings in other indications. For neuroendocrine tumors the results are particularly exciting as they do not only demonstrate that uTRACE® may be valuable for planning of therapy and follow-up (prognostic value), but since uPAR was demonstrated in the majority of patients it constitutes clinical support for Curasight to pursue uPAR-targeted radionuclide therapy in these patients. In particular, it should be noted that while some of neuroendocrine tumors patients today are treated with somatostatinreceptor targeted radionuclide therapy, not all are eligible for this treatment due to low/no expression of somatostatin receptors. These, in particular tumors of high grade, could potentially in the future be served by uPAR-targeted radionuclide therapy. Accordingly, Curasight will take the published information fully into consideration in the ongoing update of our strategy. However, we are already very excited about the potential use of our platform in this indication." says CEO Ulrich Krasilnikoff.



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Curasight is a clinical development company based in Copenhagen, Denmark. The company is a pioneer in the field of exploiting a novel theranostic platform with Positron Emissions Tomography (PET) imaging and Radionuclide Therapy targeting the urokinase-type plasminogen activator receptor ("uPAR"). The technology is expected to improve diagnosis, risk stratification and therapy in multiple cancer types.